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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/445,796 03/13/00 BRASSART

D P99,2625

EXAMINER

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HM12/0808

AFREMOV, V
ART UNIT PAPER NUMBER

1651

DATE MAILED:

08/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/445,796	Applicant(s) Brassart et al.
Examiner Vera Afremova	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jun 4, 2001

2b) This action is non-final.

2a) This action is FINAL.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 11-23

is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 11-23 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage

application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) Other: _____

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DETAILED ACTION

Claims 1-10 were canceled by applicants in the Paper No. 10 filed 6/04/2001.

New claims 11-23 are pending and under examination.

Specification

The disclosure is objected to because of the following informalities: section "Brief description of drawings" is missing. Appropriate correction is required.

Drawings

The drawings are objected to because they are not in English. Correction is required.

Response to Arguments

Applicants' arguments filed 6/04/2001 have been fully considered however some of them are not found persuasive for the reasons below.

Deposit

The deposit requirement for *Lactobacillus johnsonii* CNCM I-1225 has been met in the Paper No. 10 filed 6/04/2001.

Claim Rejections - 35 U.S.C. § 112

New claims 11-23 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as explained in the prior office action and for the reasons below.

New claims remain indefinite with regard to the term "*lactobacilli*" as presently claimed.

Applicants appear to argue that this term is a plural form for the representatives of the genus

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Lactobacillus (see response page 3, last line). However, the definitions in the as-filed specification encompasses the use of **lactobacteria** of other genera, for example: *Leuconostoc* (page 3, line 17). In addition, it appears from the applicants' disclosure that representatives of the genus *Bifidobacterium* are also regarded as "*lactobacilli*" or lactobacteria which are capable to produce effects as intended (page 2, line 7). Thus, it remains uncertain what is the group of bacteria which is claimed. Are they lactobacteria which are capable to produce lactic acid and to low pH? Or are they representatives of the genus *Lactobacillus* only as appears to be argued?

Claim Rejections - 35 U.S.C. § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New claims 11-13 and 15-23 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,578,302 [B].

New claims 11-23 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,494,664 [A].

The claims are directed to a method for improving absorption of minerals from the diet wherein the method comprises enterally administering to a mammal a nutritional composition which contains lactobacteria. Some claims are further drawn to the use of *Lactobacillus sp.* CNCM I-1225 in the method of administration of the nutritional composition. Some claims are further drawn to the use of lactobacteria in amounts 10^x7 to 10^x11 CFU/ml in the method of

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administration of the nutritional composition. Some claims are further drawn to the use of milk products and/or milk hydrolysates in the nutritional composition in the method of administration.

The cited US 5,578,302 [B] and US 5,494,664 [A] are relied upon as explained in the prior office action and repeated herein.

US 5,578,302 [B] (abstract) teaches a method for improving mammal health wherein the method comprises enterally administering to a mammal a nutritional composition which contains lactobacteria including *Lactobacillus sp.* CNCM I-1225 (col.2, line 13) in nutritional composition in a form of yogurt or milk-based powdered formulations (col.1, lines 43-44).

US 5,494,664 [A] (col. 1, line 43-60 and col. 2, line 14) teaches a method for improving mammal health wherein the method comprises enterally administering to a mammal a nutritional composition which contains lactobacteria and/or bifidobacteria including *Lactobacillus johnsonii* CNCM I-1225 in amounts 10^x7 to 10^x8 CFU/ml in nutritional composition in a form of yogurt or other milk-based product.

With regard to US'664 and US'302 applicants argue that the cited patents do not suggest capability of lactobacteria for improving absorption of minerals from the diet. This is not found persuasive because the cited methods and the presently claimed method are one active step methods comprising one step of enterally administering to a mammal an identical composition with identical lactobacteria belonging to identical strain *Lactobacillus sp.* CNCM I-1225 {US'664 or US'302} at identical amount such as 10^x7 to 10^x8 CFU/ml {US'664}. Thus, the final result as

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disclosed and as claimed is inherently identical as the result of administration of identical composition with identical lactobacteria.

Claim Rejections - 35 U.S.C. § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New claims 11, 14- 20 and 23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yaeshima [IDS-3-AR] and Yoshida [U].

The claims are directed to a method for improving absorption of minerals from the diet wherein the method comprises enterally administering to a mammal a nutritional composition which contains lactobacteria or bifidobacteria. Some claims are further drawn to the use of milk products and/or prebiotic fibers or oligosaccharides in the nutritional composition in the method of administration.

The cited references by Yaeshima [IDS-3-AR] (page 41) and Yoshida [U] are relied upon as explained in the prior office action and repeated herein.

The cited references by Yaeshima [IDS-3-AR] (page 41) and Yoshida [U] (abstract) disclose a method for increasing absorption of minerals from the diet wherein the method comprises enterally administering to a mammal a nutritional composition with lactobacteria or bifidobacteria alone or with additional products such as dietary fibers (oligosaccharides or lactulose) and minerals (calcium, magnesium, etc.).

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The referenced methods appear to be identical to the presently claimed method and are considered to anticipate the claimed invention since they are one active step methods of administering identical nutritional compositions with live lactobacteria or bifidobacteria alone or with additional products such as dietary fibers (oligosaccharides or lactulose) and minerals (calcium, magnesium, etc.) to identical patients for improving absorption of minerals. Consequently, the claimed method of administration appears to be anticipated by the cited references.

In the alternative, even if the claimed method is not identical to the referenced methods with regard to particular microbial cultures in the nutritional composition intended for administration or with regard to some others unidentified characteristics, the differences between that which are disclosed and that which are claimed are considered to be so slight that the referenced methods are reasonably believed to produce identical effects with regard to absorption of minerals as it is taught by the cited references. Or substitution of one lactobacterium or bifidobacterium for another lactobacterium or bifidobacterium in the method of administration is likely to be substitution of equivalents. And, thus, the claimed method of administration would have been obvious to those of ordinary skill in the art within the meaning of U.S.C. 103. Therefore, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

With regard to the cited references applicants seem to argue that they fail to teach the use of "lactobacilli" or lactobacteria in the method of administration for improving absorption of

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minerals. However, the claimed method does not exclude the use of lactic acid producing bacteria belonging to the genera others than *Lactobacillus*. The term “*lactobacilli*” appears to include a variety of bacteria according to the as-filed specification (page 3, line 17). And the particular effects as intended are also demonstrated for various bacteria belonging to the various genera such as *Lactobacillus* and/or *Streptococcus*, for example (see figures 2-3 and see page 9, lines 1-5). The “hypothesized” mechanism of improving absorption of minerals by lactobacteria is regarded by applicants as the result of acidification (see response page 5, par. 2). And it is known that bacteria belonging to *Bifidobacterium* as well as *Lactobacillus* produce lactic acid (see the attached reference by Bergey's at page 574, col.1, line 4, for example). Moreover, the cited reference by Yaeshima [IDS-3] teaches representatives of *Bifidobacterium* and *Lactobacillus* as equivalents in the nutritional composition such as acidified milk/yogurt or “Bifidus milk” (page 38, col.2 , line 3). Thus, applicants' argument drawn to the idea of exclusion of bifidobacteria and/or to the exclusive capability of only “*lactobacilli*” to acidify environment and to improve absorption of minerals in the method of administration does not appear to have persuasive grounds.

Some applicants arguments seem to the drawn to the idea that lactobacteria are capable to improve mineral absorption without additional fibers or oligosaccharides (see response page 8, par. 2). Yet, the claimed method is directed to the use of prebiotic fibers (claim 18, for example) or oligosaccharides (specification page 5, line 35). And the cited reference by Yaeshima [IDS-3] teaches that absorption of minerals has been improved as the result of administration of both

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compositions with and/or without oligosaccharides over control diet (figure 13). The disclosure by the Yosida's reference [U] is limited with regard to additional components and theirs effects in the method of administration of lactic acid producing bacteria for absorption of minerals. Nevertheless, it teaches the same, if not identical, method of administering lactic acid producing bacteria to mammal with the same, if not identical, effects at least as related to "treatment or prophylaxis" of mineral absorption or deficiencies as it is encompassed by the present invention and/or claims. And, thus, he claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Claim Rejections - 35 U.S.C. § 103

Claims 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,578,302 [B] or US 5,494,664 [A] taken with Yaeshima [IDS-3-AR] and Yoshida [U].

The claims as explained above.

The cited patents US 5,578,302 [B] or US 5,494,664 [A] are relied upon as explained above. The cited methods are silent with regard to the intended effects such as improvement of mineral absorption as the result of oral administration of lactobacteria.

However, the references by Yaeshima [IDS-3-AR] and Yoshida [U] teaches method for treatment and/or improving mineral absorption by administering lactobacteria or bifidobacteria to mammals.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute bacterial strains belonging to the genus

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Lactobacillus for the representatives of the genus *Bifidobacterium* in the method of administering *Lactobacillus* or *bifidobacteria* to mammals with a reasonable expectation of success in treating lactobacteria or bifidobacteria to mammals with a reasonable expectation of success in treating and/or improving mineral deficiencies and/or absorption because bacteria belonging to *Lactobacillus* and *Bifidobacterium* have been taught and demonstrated as equivalents in the nutritional compositions intended for mammal health improvement. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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August 6, 2001.



FRANCISCO PRATS
PRIMARY EXAMINER